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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,604	02/05/2004	Thomas Roballey	1330.004	7751
24126	7590	09/19/2006	EXAMINER	
ST. ONGE STEWARD JOHNSTON & REENS, LLC 986 BEDFORD STREET STAMFORD, CT 06905-5619			SNOW, BRUCE EDWARD	
			ART UNIT	PAPER NUMBER

3738

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/773,604

Applicant(s)

ROBALLEY, THOMAS

Examiner

Bruce E. Snow

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3, 12, 13 and 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3, 12, 13 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 7/13/06 have been fully considered but they are not persuasive. Applicant argues the lumen of that the gastro-intestinal tract develops from the modifications of the primitive gut that forms a continuous elongated tube from the mouth to the anus, and the lumen thereof is considered to be exterior to the tissues of the body and is not within the tissue of the patient's body. The Examiner finds this argument creative, but again, not persuasive. Giving the claim language it's broadest reasonable interpretation, one skilled in the art would consider a device placed in the stomach to fulfill the new limitations, "for placement internally within tissues at a location of the patient body" and "interacting with surrounding bodily tissues". Surely the stomach is tissue, not metal or plastic, and the device 70 is within the tissue stomach and interacts therewith. Additionally, referring to figure 7 of Torre et al, sutures 71 extend through the wall the stomach. In conclusion the device of Torre et al meets these limitations in both the device claim and method claims.

Regarding claim 3, the new limitations, "for placement internally within tissues at a location of the patient body" and "interacting with surrounding bodily tissues" are considered only functional language. MPEP 2114 teaches:

2114 Apparatus and Article Claims - Functional Language [R-1]

APPARATUS CLAIMS MUST BE STRUCTUR-ALLY DISTINGUISHABLE FROM THE PRIOR ART

While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather

than function. *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997).

It is the Examiner's position that the device of Torre et al can function as claimed and placed within tissues.

Regarding applicant's arguments that one skilled in the art would not be motivated to use methylene blue dye as taught by Torre et al because it is "teratogenic", please read your specification, i.e. page 12, line 7, teaching it as a rupture indicator.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3, 12, 13, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Torre et al (2002/0055757).

Torre et al teaches:

A prosthesis for implant 70 in a human patient body comprising:

at least one elastomeric envelope 140,

a filling material contained in the elastomeric envelope; see at least paragraphs 0091 and 0092; and

a biologically compatible chemical rupture indicator contained within the elastomeric envelope capable of leaking out of the envelope and causing a body

change detectable to the patient, wherein the body change detectable to the patient is a change in a body secretion selected from the group consisting of urine, saliva, perspiration, feces, and combinations of these; see at least paragraph 0092 stating, *"the filling material may also include barium sulfate (BaSO₄) or a similar agent so it can be seen on x-ray; or blue dye, such as methylene blue, such that the patient would notice a change in urine color that would signify a leak or other break in the device barrier."*

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E. Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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BRUCE SNOW
PRIMARY EXAMINER